REMARKS

Claim 2 has been cancelled and claims 1 and 3-16 have been amended. Claims 1 and 3-16 remain for further consideration. No new matter has been added.

The rejections and objections shall be taken up in the order presented in the Official Action.

1. Claims 1-7 currently stand rejected for allegedly being anticipated by the subject matter disclosed in U.S. Patent 4,819,621 to Ueberle et al (hereinafter "Ueberle").

Claim 1 recites a method of applying extracorporeally generated acoustic pressure waves to the body of an organism. The method comprising:

> "applying extracorporeally generated acoustic pressure waves to target tissue of the body;
>
> detecting cavitation bubbles within the target tissue of the body caused by applying the extracorporeally generated acoustic pressure waves by receiving an acoustic signal at an extracorporeal detector and providing a received acoustic signal indicative thereof; and
>
> processing the received acoustic signal to determine if cavitation bubbles are present within the target tissue of the body, and controlling the extracorporeally generated acoustic pressure waves based upon the received acoustic signal." (emphasis added, cl. 1).

Significantly, the method of claim 1 applies the pressure waves, detects cavitation bubbles causes by the pressure waves, and then controls the pressure waves based upon the received acoustic signal indicative of the cavitation bubbles caused by the pressure waves. In contrast, Ueberle discloses a system that applies test pulses in order to detect cavitation actions for proper positioning of a sonic transducer 1. As shown in FIG. 1 of Ueberle, a generator 5 generates high sonic energy that is used to destroy a section present within a target area. A test pulse generator 6 is used to merely provide a test pulses used

in positioning of the transducer 1 – not control of the pressure waves. Specifically, Ueberle states:

> "When test pulses are to be generated for detection of cavitation actions, the test pulse generator 6 is activated by the control stage, whereas the generator 5 is deactivated, so that the transducer 1, now supplied with current pulses from the [test pulse] generator 6 transmits acoustic test pulses 7 into the target zone." (col. 4, lines 9-14).

Ueberle further states:

> "Following the indication and recognition of cavitation actions, the focus of the sonic transducer 1 should be aligned again corrected on the concretion which is to be destroyed, which may be preformed by appropriately repositioning the patient with respect to the sonic transducer." (col. 4, lines 58-63)

Hence, a fair and proper reading of Ueberle indicates that Ueberle discloses using a test pulse to detect cavitation for positioning of the patient with respect to the transducer 1. In contrast, claim 1 of the present invention applies the pressure waves to target tissue of the body, detects cavitation bubbles caused by the pressure waves, and then controls the pressure waves based upon the received acoustic signal indicative of cavitation bubbles caused by the pressure waves. That is, the method of the present invention detects cavitation bubbles caused by the pressure waves and then adjusts the pressure waves in the event cavitation is caused by the pressure waves (not a separate and distinct test pressure wave as disclosed in Ueberle).

As a result, it is respectfully submitted that Ueberle is incapable of anticipating the subject matter recited in claim 1.

2. Claims 8-16 currently stand rejected for allegedly being obvious in view of the combined subject matter disclosed in Ueberle and U.S. Patent 4,689,986 to Carson (hereinafter "Carson"); or in view of the combined subject matter disclosed in Ueberle and U.S. Patent 6,461,586 to Unger (hereinafter "Unger").

The Official Action recognizes that Ueberle fails to disclose regulating treatment energy. (see Official Action, pg. 3). However, the Official Action then alleges that Carson and Unger disclose such a feature and that a person of ordinary skill in the art at the time of the invention would have been motivated to modify Ueberle based upon the teachings of either Carson or Unger in order to accurately apply extracorporeal generated pressure waves in a region of interest (see Official Action, pages 3-4).

Assuming for the moment, without admitting that Ueberle and Carson are even properly combinable, if these two references were combined as suggested in the Official Action, the resultant combination is still incapable of rendering claim 8 obvious. Specifically, even if Ueberle is modified so the pressure wave energy is adjusted as suggested in the Official Action, then the result system is still only adjusting the **test** pressure wave, since the **test** pressure wave is the one used in Ueberle to check for cavitation bubbles. A second, higher power pressure wave (from generator 5 in the FIGURE of Ueberle) is used in Ueberle for the medical treatment. In contrast, in claim 8 the pressure wave used to check for the presence of cavitation bubbles is the same pressure wave used for the medical treatment. Thus, even if the power of the test pressure wave of Ueberle is adjusted based upon the alleged teaching of Carson as suggested in the Official Action, then the resultant system is still not the claimed invention, since the power of the test pressure wave would be adjusted in the combined teachings of Ueberle and Carson, rather than the power of the pressure wave used for medical treatment. Accordingly, it is respectfully

submitted that the combined teachings of Ueberle and Carson are incapable of rendering the obvious the subject matter recited in claim 8.

Similarly, the combination of Ueberle and Unger is also incapable of rendering the subject matter of claim 8 obvious. Claim 8 recites a device for applying extracorporeally generated acoustic pressure waves to the body of an organism. The device includes:

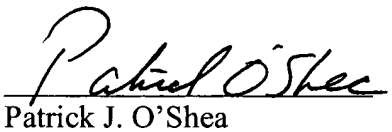
> "a pressure wave generator **that generates an acoustic pressure waves**;
> a treatment head that is operatively connect to the pressure wave generator and applies the acoustic pressure waves to a target area of the body;
> an acoustic detector brought in contact with the surface of the body to record acoustic signals from cavitation bubbles generated **by the pressure waves** and provide an detected signal indicative thereof; and
> an electronic evaluation device that receives the detected signal and controls parameters **of the acoustic pressure waves** in response to the detected signal." (emphasis added, cl. 8).

Notably, the detector recited in claim 8 checks for cavitation bubbles caused by the acoustic pressure waves, and the electronic evaluation device controls parameters of the acoustic pressure waves in response to the detected signal indicative of the acoustic pressure waves. In contrast, if Ueberle is modified based upon the teachings of Unger as set forth in the Official Action, the resultant system would merely adjust the **test** pressure wave, since the **test** pressure wave in Ueberle is the one used to check for cavitation bubbles. In Ueberle, a separate higher power pressure wave from the generator 5 is the one used for the medical treatment. Accordingly, it is respectfully submitted that assuming for the moment without admitting that Ueberle and Unger are even properly combinable, the resultant combination still fails to render obvious the device set forth in claim 8 for at least the reason that the resultant combination fails to disclose using the same pressure wave that is used for the medical treatment to also check for cavitation bubbles.

Reconsideration and allowance of claims 1, 3-16 is respectfully requested.

If a telephone interview could assist in the prosecution of this application, please call the undersigned attorney.

Respectfully submitted,



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~~Description~~

~~Method~~METHOD ~~and~~ AND ~~Device~~ DEVICE FOR~~for Applying~~ APPLYING ~~Pressure~~ PRESSURE ~~Waves~~ WAVES ~~to the~~TO THE ~~Body of an Organism~~ BODY OF AN ORGANISM

BACKGROUND OF THE INVENTION

The invention relates to a method and device for applying extracorporeally generated acoustic pressure waves to the body of an organism.

Acoustic pressure waves are applied in medicine in various forms, for example, as ultrasound waves, as pulsed ultrasound waves, and as shock waves.

Acoustic shock waves are characterized by a short positive pressure pulse exhibiting a steep rise and high amplitude followed by a negative pressure pulse of low amplitude and of longer time. There exists in medicine the known method of applying such acoustic shock waves, for example, for destroying bodily concretions, and kidney stones in particular. Shock waves are similarly used to stimulate bone growth or to treat the tissue of soft body parts. During treatment, the shock wave dosages are generally determined empirically. Pulse energy, penetration depth, application frequency, and number of applications are generally selected based on experience. This means that the treatment requires a great amount of experience on the part of the physician – a factor which is disadvantageous for the use of such equipment. Additionally, the therapeutic success of these empirical methods is often not optimal since an excessively low dose reduces the

desired success rate, while an excessively high dose can result in undesirable damage to the tissue not targeted for treatment.

Therefore, there is a need for~~The object of the invention is to provide~~ a method and device for applying extracorporeally generated acoustic pressure waves to the body of an organism, specifically shock waves, which method and device offer a high level of control and dosing of the effect of the pressure waves.

SUMMARY OF THE INVENTION

~~This object is achieved according to the invention by a method having the characteristic features of Claim 1 and a device having the characteristic features of Claim 8.~~

~~Advantageous embodiments of the invention are provided in the referenced subclaims.~~

The invention is based on the known principle first of all that the application of pressure waves to bodily tissues, specifically shock waves, may be associated with a cavitation effect. This cavitation is produced by the fact that gas bubbles within the tissue are affected by the pressure of the shock wave. The positive pulse of the shock wave causes the gas bubbles to be compressed, while the subsequent negative pressure amplitude results in the small gas bubbles expanding and enlarging. The occurrence of such cavitation bubbles is thus an indicator of the effect of the shock wave. In addition, cavitation bubbles may also be generated by shock waves when the treated medium is inhomogeneous or contaminated. Nonhomogeneities or impurities act as seeds for cavitation.

The creation of cavitation bubbles can be detected acoustically (Cleveland, Sapozhnikof, Bailey and Crum, " A Dual Passive Cavitation Detector for Localized Detection of Lithotripsy-Induced Cavitation in Vitro," J. Acoust. Soc. Am. 107 (3), March 2000). The cavitation bubbles generate an acoustic signal which, as a rule, occurs as a double signal, the first signal indicating the compression of small bubbles by the positive pressure pulse, and a second signal being generated with a delay when the cavitation bubbles enlarged by the negative pressure amplitude collapse again. The cavitation bubbles may be recorded and localized by acoustic detectors on the basis of these acoustic signals.

According to the invention, for treating the body of an organism, i.e., a human being or an animal, at least one acoustic detector may be disposed extracorporeally for the purpose of detecting and possibly localizing the cavitation bubbles created by application of the shock wave. By detecting the cavitation bubbles, the effect of the shock wave within the treated tissue may be recorded by measuring equipment. The physician applying the treatment is thus no longer dependent on values gained from experience to set the dosage for the shock waves, but is able to optimize the dosage individually for each treatment.

The course of treatment with pressure waves may, for example, begin with a low pulse energy level at which no cavitation ~~so far~~ occurs, i.e., the acoustic detectors do not yet receive any signals. The pulse energy of the shock wave or pressure wave is then increased. The adjustment of or increase in the energy level is performed based on the technique used to generate the shock waves, for example, electrohydraulic, electromagnetic, piezoelectric, or ballistic generation.

When generating the shock wave by spark discharge, for example, the applied high voltage may be increased. The onset of cavitation here is determined acoustically by the detector. A further increase in the pulse energy results in a stronger cavitation effect. By acoustically monitoring the cavitation effect, the energy of the shock wave may be set to that value which on the one hand achieves the best therapeutic effect, while on the other hand avoids excessive energy producing a damaging effect without improving the therapeutic effect.

The optimum pulse parameters for the shock wave may be determined and set within one, or a very few, applications. Subsequent treatment may then be optimally administered using the shock wave parameters set by this procedure.

The method according to the invention and device according to the invention are especially well suited for automatic control. The shock wave parameters required for optimal treatment are set as the target value for the associated cavitation effect. The cavitation produced by the shock waves is then measured by the extracorporeal detector as the actual value and the shock wave parameters are automatically adjusted to set the measured actual value of cavitation to match the specified target value.

Based on the measurement of the shock wave effect of cavitation, the desired treatment may be performed in an optimal manner with no physician experience or physician intervention being necessary. The shock wave or pressure wave, i.e., the energy, pulse shape, pulse sequence, rise time, tension component, etc. of the wave, or the focus position as well, must simply be adjusted, either manually or by automatic control, such that the measured cavitation matches the specified

value. Since the shock wave generation occurs within the treatment target area in accordance with the actual effect really measured, the result is that: differences in tissue structure from patient to patient are automatically taken into account; varying attenuations of the shock waves as they pass through the body to the target area, for example due to the tissue structures traversed, tissue thickness, etc. are compensated; changes in the tissue structure, for example, due to the respiratory movements of the patient, are taken into account; and finally, even short-term changes in the tissue structure, for example, due to the effect of the shock waves themselves are compensated.

The acoustic measurement of the effect of the shock waves within the target area may also be exploited in other ways. The dependence of the cavitation bubble formation on the tissue structure may, for example, be exploited to analyze the tissue structure, composition or differentiation by ease ~~means~~ of predetermined shock waves.

If pressure waves of predetermined energy levels are introduced into the body, the interfaces between the various tissue materials may be determined based on the changing cavitation effect at this interface. This factor may, for example, be advantageously exploited when shock waves are applied to bone in order to stimulate bone growth. The discontinuous changes in the cavitation effect at the bone surface allow for a precise focusing or positioning of the shock wave, or detection of the interface.

In addition, the tissue structure may be scanned over a greater spatial area to obtain an image of the tissue anatomy. To accomplish this, a pressure wave with ~~a~~ predetermined parameters may

be applied to a larger target area, and the cavitation bubble formation which changes locally according to the varying tissue structure may be differentially scanned using focused detectors.

The reverse procedure is also possible in which the spatial pressure field of the pressure wave is determined and displayed within a known tissue structure of the target area based on the measured spatial distribution of the cavitation effect, for example, as a mechanism ~~means~~ for determining and controlling the focus of the shock wave source.

These and other objects, features and advantages of the present invention will become more apparent in light of the following detailed description of preferred embodiments thereof, as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

~~The following discussion explains the invention in greater detail based on several embodiments.~~ The FIGURE~~igure~~ 1 shows a device according to the invention in schematic form.

DETAILED DESCRIPTION OF THE INVENTION

The FIGURE~~igure~~ 1 shows a shock wave generator 1 with a treatment head 2. The shock wave generator 1 contains the familiar power and voltage supply together with the associated control electronics. The ~~T~~treatment head 2 is a familiar pressure wave or shock wave generator and has, for example, a volume of liquid with a shock wave source including~~consisting~~, for example, of two high-voltage electrodes, piezoelements, etc. The ~~T~~treatment head 2 is placed on

the surface of the body of the human or animal subject undergoing treatment and can inject the shock waves generated in the treatment head 2 into the body and focus them in a target area inside the body.

In addition, the device has at least one acoustic detector, preferably two detectors, which are identified as 3a and 3b. Additional analogously designed detectors may be used as required. The ~~D~~detectors 3a, 3b are microphones or hydrophones which are placed preferably extracorporeally on the body surface. The ~~D~~detectors 3a, 3b are preferably focusable so that they may receive directed acoustic signals from a defined target area.

The acoustic signals are received and ~~from detectors 3a, 3b are~~ converted by the detectors 3a, 3b into electrical signals which are fed to an electronic evaluation device ~~means~~ 4. When two or more detectors 3a, 3b are employed, the electronic evaluation device ~~means~~ contains specifically a coincidence device which assigns the signals received from the detectors 3a, 3b to the same event, i.e., to the same cavitation bubbles. The overall function of the electronic evaluation device ~~means~~ 4 is to qualify the measured cavitation effect and, for example, to indicate the location, size, lifetime, quantity and/or density of the cavitation bubbles. The signals analyzed in the electronic evaluation device ~~means~~ 4 are displayed in a display unit 5. Presentation of the signals in the display unit 5 may be accomplished in different ways. The simplest type of display includes ~~consists of~~ a luminous indicator which shows simply whether or not acoustic signals are being received. A more informative display may include ~~consist of~~ three display lamps which indicate respectively whether the effect of the shock wave introduced by the treatment head 2 into the target area lies below, at, or above the cavitation threshold. It is also possible to equip the

display unit 5 with an analog display, for example, a meter or a light-strip indicator which displays quantitatively the acoustic signals of the cavitation bubbles received by the detectors 3a, 3b.

The signals processed by the electronic evaluation device ~~means~~ 4 are also fed to a feedback system 6 which may be provided in addition to the display unit 5 or which may completely replace the display unit 5.

The ~~F~~feedback system 6 may perform the following functions which may be provided either in combined form or as alternatives. The f~~F~~eedback system 6 may act on the shock wave generator 1 through automatic control 6a to control the adjustment parameters for the treatment head 2 such that the actual value of cavitation measured by the detectors 3a, 3b is adjusted to match a specified target value. In addition, the feedback system 6 may use an actuating signal generator 6b to generate actuating signals for the alignment mechanism of the detectors 3a, 3b. Finally, the feedback system 6 may generate data for an image-processing system 7 via an image generator 6c.

The device according to the invention offers the following possible applications.

When a certain region of a patient's body is to be treated with shock waves, the treatment head 2 is placed on the patient's body and focused on the target area. The ~~D~~detectors 3a, 3b are similarly placed on the surface of the body and focused on this target area. When the shock wave generator 1 is operated, the detectors 3a, 3b measure the effect of the shock waves produced by the

cavitation bubbles in the target area. The effect of the shock waves in the target area is displayed by the display unit 5. Based on the information indicated by the display 5, the operators may adjust the shock wave generator 1 to achieve the desired shock wave effect within the target area. When the feedback system 6 is used, a target value for the shock wave effect may be specified for the control unit 6a, which value is automatically adjusted by the shock wave generator 1. In this way, the shock wave treatment of the target area may be performed, for example according to the principle "as much as necessary, as little as possible."

When a defined, locally limited target area is to be treated with shock waves, the shock waves emitted by the treatment head 2 are focused on this target area. As a result, the effect of the shock waves and the formation of cavitation bubbles is accordingly the strongest in this target area. Since the cavitation bubbles are thus first created in this target area as the shock wave energy increases, a single detector 3 may be sufficient for a single measurement, although this detector 3 does not need to be focused on the target area. A simple determination of the cavitation threshold within the target area may be performed by a single integrally measuring, unfocussed detector 3.

The employment of focused detectors 3 and of two or more detectors 3a, 3b additionally allows for a more precise spatial measurement of the cavitation. In this approach, noise signals may be blanked out. When there is a higher dosage of shock waves resulting in a stronger propagation of the cavitation effect, the shock wave effect may be measured within a specific target area. Similarly, the spatial distribution of the shock wave effect may be determined by the focused detectors 3a, 3b.

A measurement of coincidence using the two focused detectors 3a, 3b makes it possible to localize spatially the initiation site of the acoustic signals within a volume with a diameter of 0.2 mm to 20 mm. As a result, it is possible to differentially scan the cavitation bubbles created by the shock waves in terms of their spatial distribution and intensity as well. To achieve this, the detectors 3a, 3b may be moved three-dimensionally and aligned – a task which may, as appropriate, be accomplished by actuating the signal generator 6b of the feedback system 6. Using the image generator 6c of the feedback system 6 within the image-processing system 7, the spatial distribution and intensity of the created cavitation bubbles measured by this spatial scanning procedure may be displayed three-dimensionally on a monitor and/or recorded.

Measurement of the spatial distribution and intensity of the generated cavitation bubbles by the focused detectors 3a, 3b, and by possible additional detectors within a coincidence circuit, provides for the following additional applications.

When the shock wave field in the bodily tissue is scanned differentially and three-dimensionally by the detectors 3a, 3b, differences in the tissue structure may be determined based on the changes in the cavitation effect. Specifically, interfaces between the different tissue materials may be determined which are associated with a discontinuity in the impedance of the transmitted shock waves and with an increased shock wave reflection. This feature may, for example, be utilized to determine the surface of a bone undergoing treatment, a calcium deposit to be destroyed, or a bodily concretion so that the shock waves may be focused or precisely positioned on this target area.

In addition, the anatomical tissue structure within a larger spatial region may be mapped and imaged as required. To achieve this, the shock wave field generated by the treatment head 2 and the focus area of the detectors 3a, 3b are simultaneously displaced. The fact that the measured cavitation signal in response to an identical shock wave effect depends on the character of the specific targeted tissue allows a three-dimensional graphic representation of the tissue structure to be obtained. A corresponding determination of the tissue structure may be obtained by measuring the cavitation threshold of the shock wave energy level at which cavitation begins for each target point of the three-dimensional region.

An additional possibility is to use the focused detectors 3a, 3b to map the shock wave field generated by the treatment head 2 three-dimensionally. Given a known tissue structure which has, for example, been measured by ultrasound, the shock wave field caused by cavitation is mapped three-dimensionally. Based on the known spatial distribution of the tissue structure and the measured cavitation, the spatial distribution of the shock wave effect, and thus the spatial pressure field, may be computationally analyzed and displayed as required.

~~List of Reference Numbers~~

~~1 Shock wave generator~~

~~2 Treatment head~~

~~3a/3b Detectors~~

~~4 Electronic evaluation means~~

~~5 Display unit~~

~~6 Feedback system~~

~~6a Control unit~~

~~6b Actuating signal generator~~

~~6c Image generator~~

~~7 Image processing system~~

Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.

What is claimed is: